(d) a bulking agent selected from the group consisting of mannitol and sucrose.

14. (Amended) The GLP-2 formulation of claim 13, wherein the GLP-2 peptide has the sequence of a GLP-2 species from an animal selected from the group consisting of a primate, rat, mouse, porcine species, oxine species, bovine species, degu, hamster, guinea pig, fish, chicken, and human.

15. (Amended) The GLP-2 formulation of claim 14, wherein the GLP-2 peptide is h(G1y2)GLP-2.

32. (Amended) The GLP-2 formulation of claim 31, wherein the GLP-2 is h(G1y2)GLP-2.

REMARKS

I. Status of the Claims

By this amendment, claims 1, 14, 15, and 32 are amended. Upon entry of this Amendment, claims 1-54 will remain pending in the application.

Claim 1 has been amended to recite a "glucagon-like peptide-2 (GLP-2)", rather than "GLP-2;" claim 14 has been amended to correct a spelling error; and claims 15 and 32 have been amended to replace the recited brackets with parentheses. Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Issues Regarding Perfection of the Claimed Foreign Priority

The examiner asserted that applicant claims foreign priority; however, the priority document (United Kingdom 993-882.7) has not been submitted. Submitted herewith, as Exhibit 1, is a certified copy of the priority document.

III. Claim Objections

Claim 14 was objected to for the recitation of "n animal". Applicant has amended claim 14 to recite "an animal". Therefore, withdrawal of the rejection is respectfully requested.

Claims 15 and 32 were objected to for the use of brackets. Applicant has amended claims 15 and 32 by changing the brackets to parentheses. Therefore, withdrawal of the rejection is respectfully requested.

IV. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 1-54 were rejected under 35 U.S.C. § 112, second paragraph, because the claims are allegedly indefinite. Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claims 1-54 were rejected because the term "GLP-2" is allegedly indefinite. Applicant has amended claim 1 to recite "glucagon-like peptide-2 (GLP-2)".

Claims 1-14, 17, and 22-54 were rejected because the term "an analog" is allegedly indefinite. Applicant respectfully disagrees. A person of ordinary skill in the art would understand the meaning of the term "an analog" in the context of the present application. For example, applicant directs the Examiner's attention to page 5, line 24, through page 6, line 28, where GLP-2 analogs are clearly described. As the present specification provides a detailed description of the term "analog", the term "an analog" as used in claims 1-14, 17, and 22-54 is not indefinite.

Claims 2 and 3 were rejected because the phrases "greater than about 6.0" and "from about 6.9 to 7.9" are allegedly indefinite. The examiner applied the same rejections to claims 4, 34, 35, 37-41, 44, 45, 50, and 51. Claims 23 and 25 were rejected by the examiner because the phrases "less than about 5%", "for up to at least 6 months", and "less than about 3 to about 4%" are allegedly indefinite. The examiner extended this rejection for the same reasons to claims 26-30, 41, and 47. Finally, claim 48 was rejected by the examiner because

the phrase "up to about 24 hours" is allegedly indefinite. Applicant respectfully disagrees and asserts that these terms do not render the claims indefinite. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, (Fed. Cir. 1983) and *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968). A person of ordinary skill in the art would know that the phrases refer to measurement variability.

Claim 17 was rejected by the examiner because the phrases "one or more amino acid substitutions, additions, deletions or modifications" and "biological activity" are allegedly indefinite. Applicant respectfully disagrees.

With respect to "one or more amino acid substitutions, additions, deletions, or modifications", a person of ordinary skill in the art would know the meaning of this term within the context of the specification. For example, applicant directs the Examiner's attention to page 6, lines 4-23, of the specification where specific amino acid substitutions, additions, deletions or modifications are described. As the present specification provides a detailed description of specific amino acid substitutions, additions, deletions, or modifications in the context of the present specification, the phrases "one or more amino acid substitutions, additions, deletions, or modifications" is not indefinite.

Turning to "biological activity", applicant asserts that a person of ordinary skill in the art would know the meaning of this term within the context of the specification. For example, the Examiner's attention is directed to page 1, lines 21-23, of the specification where it is stated that "GLP-2 and analogs thereof act as trophic agents to enhance and maintain the functioning of the gastrointestinal tract and to promote growth of intestinal tissue." As the present specification clearly describes the biological activity of GLP-2 and analogs thereof, the phrase "biological activity" is not indefinite.

Claims 49-54 were rejected because the terms "a disorder, disease, or condition" and "gastrointestinal disease" are allegedly indefinite. Applicant respectfully disagrees. A person of ordinary skill in the art would know the disorders, diseases, and conditions, including gastrointestinal diseases, for which treatment with GLP-2 is indicated. For example, on page 7, lines 27-33, of the specification, it states "[t]herapeutically useful amounts of GLP-2

include those unit dosage amounts useful in a regimen to treat a subject that would benefit from GLP-2 administration, as described more fully in U.S. Patent Nos. 5,834,428; 5,789,379; 5,990,077; and 5,952,301, and in International Publication No. WO 98/52600." A person of ordinary skill in the art would refer to these documents to determine disorders, diseases, or conditions for which treatment with GLP-2 is indicated. Therefore, the terms "a disorder, disease or condition" and "gastrointestinal disease" are not indefinite within the context of the present specification.

Claims 49-54 were rejected because the claims allegedly lack essential steps in the method of treating a human or an animal having a disease using the GLP-2 formulation. Applicant respectfully disagrees. Claim 49 is a proper method claim. The "steps" that the Examiner states are missing from the claims are not steps, but instead, are details about the method that are not necessary to make the claim a proper method claim. The method of administration and the effective amount of formulation are factors that can easily be determined by a person of ordinary skill in the art and are described in the specification at, for example, page 7, lines 27-33. A person of ordinary skill in the art would also know that the outcome of the treatment is to treat the disorder, disease, or condition for which treatment with GLP-2 is indicated.

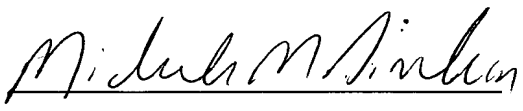
CONCLUSION

As the above-presented amendments and remarks address and overcome all of the rejections presented by the Examiner, withdrawal of the rejections and allowance of the claims are respectfully requested.

If the Examiner has any questions concerning this application, he or she is requested to contact the undersigned.

Respectfully submitted,

Date June 10, 2002 (Monday)

By 

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A GLP-2 formulation comprising:

(a) a medically useful amount of a naturally occurring [GLP-2 peptide] glucagon-like peptide-2 (GLP-2) or an analog thereof;

(b) a phosphate buffer in an amount sufficient to adjust the pH of the formulation to a physiologically tolerable level;

(c) L-histidine; and

(d) a bulking agent selected from the group consisting of mannitol and sucrose.

14. (Amended) The GLP-2 formulation of claim 13, wherein the GLP-2 peptide has the sequence of a GLP-2 species from [n animal] an animal selected from the group consisting of a primate, rat, mouse, porcine species, oxine species, bovine species, degu, hamster, guinea pig, fish, chicken, and human.

15. (Amended) The GLP-2 formulation of claim 14, wherein the GLP-2 peptide is h[[]{G1y2[]]}GLP-2.

32. (Amended) The GLP-2 formulation of claim 31, wherein the GLP-2 is h[[]{G1y2[]]}GLP-2.